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BAKER & BOTTS 30 ROCKEFELLER PLAZA 44TH FLOOR NEW YORK, NY 10112			CARLSON, JEFFREY D	
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			3622	

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,790	YUAN, YILIAN	
	Examiner	Art Unit	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 May 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 1/12/06.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

1. This action is responsive to the papers filed 1/12/06 and 5/1/06.

Response to Amendment

2. The amendment filed 1/12/06 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

- While the specification appears to teach determination of abnormal data [page 5 lines 21-27], there is no teaching of removal of such detected abnormal data as now present in claims 1 and 11 and the amended specification.
- Figure 2 step 295 – no original support can be found in applicant's disclosure for returning to step 230 if the model "fails".

Applicant is required to cancel the new matter in the reply to this Office Action.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

- While the specification appears to teach determination of abnormal data [page 5 lines 21-27], there is no teaching of removal of such detected

abnormal data as now present in claims 1 and 11 and the amended specification.

- Figure 2 step 295 – no original support can be found in applicant's disclosure for returning to step 230 if the model “fails”.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- **Claims 11-17 cover subject matter incompatible with the statutory provisions of 35 U.S.C. 101 (i.e. a human as part of the system structure).**
MPEP at §2105. These apparatus claims attempt to claim structure in the form of living subject matter (i.e. the analyst) as elements of the apparatus which provide part of the “system” at least for the subjective steps of “means...for selecting...a form” and “means...for evaluating...each...form”.

4. **Additionally, Applicant's Claims 1-17 are further rejected under 35 U.S.C. 101 as failing to satisfy the “useful, concrete, and tangible result” criteria outlined in State Street.** In particular, a review of Applicant's disclosure supports the assertion that the invention defined by Claims 1-7 fails to produce a concrete and tangible result, and the invention defined by Claims 8-17 fails to produce a concrete result.

5. Concerning the issue of concreteness, Applicant's Claim 1 recites, *inter alia*, the steps of determining a market event, examining the market event, determining a

relationship between a promotion and a product, detecting a lag structure, selecting a functional form, evaluating the selected functional form, and quantifying a relationship between the promotion and product performance. System Claim 11 recites substantially similar limitations. These claim limitations are supported in the specification by discussion regarding Steps 210-270, 310-360, and 410-420.

6. Applicant states that all disclosed steps can be performed manually or using a computer. However, several of the steps in Applicant's lone explicitly disclosed embodiment require subjective decisions on the part of a human research analyst. For instance, the step of determining a market event ("Step 210") is described only in terms of manual identification (see Applicant's specification at p. 5, l. 19-20), corresponding to the step of determining a market event recited in Claims 1 and 5. Such manual identification is highly subjective, as the outcome of this step (and consequently, all steps afterward according to Figure 2) depends not only on the skill of the research analyst, but also on the investigative interest/goal and mood of this analyst. Further, not all market events can be consistently specified within a given econometric model, demonstrated by the continuing application of new models to new market-related phenomena in the literature. In particular, it is unclear whether the Box-Jenkins transfer function approach relied upon by Applicant is compatible with certain market events correlated to the explanatory variables in the lagged model (Edlund, Per-Olov, "Identification of the Multi-input Box-Jenkins Transfer Function Model," *Journal of Forecasting*, Jul-Sept 1984, Vol. 3, No. 3, 297-308, at p. 297, l. 9-13). Moreover, Applicant's method distinguishes between only two particular effects of a market event

at Steps 410 and 420. In the event the market event identified in Step 210 does not produce such readily distinguishable results (for instance, if such impact were obscured by another market event or exogenous trend), Applicant's method would fail to provide a concrete and reproducible result.

7. Several other steps also require subjective decisions to be made and have no associated teaching of an algorithmic or computer implementation of such steps. These steps include Steps 230-270 as described and recited at least at lines 8-19 of Claim 1. For example, the step of determining a relationship ("Step 230") relies upon a research analyst to specify the initial model structure (Applicant's specification at p. 5, l. 30) with no suggestion on how to distinguish among "model fitting information," "reasonableness of coefficients," and "model robustness," subjective criteria in themselves. Although suggestion is made that multiple model forms should be tried by an analyst (effectively performing Applicant's entire method multiple times), such a limitation is neither reflected in the claims nor the Figures. Regardless of the inclusion of iterations, Applicant's method and results would vary significantly and depend on the subjective judgments of a research analyst at several steps of Applicant's method. If the iterations of the method are necessary for the claimed invention to be operative, then the pending Claims require amendment to positively recite this critical element. MPEP at §2172.01.

8. More generally, results or interpretation of results from empirical methods can vary dramatically given certain model choices and subjective interpretations made along the way. For example, the outcome and interpretation of a study by R. P. Leone differs substantially from those of Wichern and Jones due to a different choice of intervention

(impulse vs. step) in modeling the impact of the American Dental Association's endorsement of Crest dental cream (see Leone, Robert P., "Forecasting the Effect of an Environmental Change on Market Performance: An Intervention Time-series Approach," *International Journal of Forecasting*, 1987, Vol. 3, 463-478, herein "Leone 1987" at p. 471, l. 3 – p. 472, l. 5; p. 472, l. 46-48). It should be noted that both studies were accepted by peer-reviewed journals and are often cited by related papers. Accordingly, given the unpredictability associated with empirical methodology, claiming subject matter pertaining to empirical methods (and associated means) concretely in the statutory sense requires more information than is disclosed by Applicant's, even considering those of ordinary skill in the art. Therefore, upon reviewing Applicant's Claims and specification, the Applicant's claimed method and associated system lacks concreteness, a judicially established requirement of 35 U.S.C. 101.

9. Addressing now the lack of tangibility, Claims 1-10 fail to recite any limitations producing a tangible result. Generally, Applicant's claims are directed to a statistical and, therefore, inherently mathematical method. The mere presence of a mathematical algorithm is not being asserted as a reason for intangibility. Instead, the claimed limitations as a whole are found to be directed to nothing more than abstract, intangible ideas. Diehr at 9.

10. Upon a review of the step limitations within the claims, the step of "quantifying a relationship" at line 17 of Claim 1 ("Step 270") appears to have been intended as the primary and tangible output of Applicant's method. However, Applicant's specification defines this step to be fitting the model specified a priori by a research analyst in Step

230 to the prescription data (Applicant's specification at p. 8, l. 17-19). At page 3, lines 23-24, the specification reads that "the relationship between the promotions and product performance is quantified by taking into account the selected functional forms."

Moreover, Applicant notes that an objective of the invention is to "accurately measure the incremental prescriptions attributable to promotions" (Applicant's specification at p. 9, l. 10-11).

11. The concept of "fit" within the art of statistics or mathematics is often applied within the context of using a regression method (e.g. ordinary least squares) to estimate the equation of a best-fit line ("line of best fit," The Penguin Dictionary of Mathematics, Penguin Books Ltd, 1989, 1998). In particular, the output of such an operation is generally an equation (or set of equations) including coefficients and/or errors (e.g. , Wichern, Dean W. and Richard H. Jones, "Assessing the Impact of Market Disturbances Using Intervention Analysis," Management Science," Nov 1977, Vol. 24, No. 3, 329-337, herein "Wichern," at p. 333, l. 19-28 and at Table 1). Thus, Applicant's step of "quantify a relationship" is interpreted as producing such an equation or equations, in accordance with the ordinary and customary meaning of "fit" in the art of time-series data analysis. However, to usefully "quantify" the relationship, the equations (or associated coefficients and errors) must undergo further mathematical and/or subjective evaluation (Wichern at p. 334, l. 3 – p. 336, l. 2) to produce a tangible result. Applicant's specification contains no teaching or suggestion to produce any such tangible result (e.g. the incremental product performance attributable to a promotion) beyond the mathematical relationship described above. In contrast, the system in State Street produced a final share price,

held to be a practical application of a mathematical algorithm, formula, or calculation.

State Street at 1601.

12. Accordingly, with respect to tangibility, Applicant's method of Claims 1-10 produces, at best, a mathematical relationship in the form of an equation or system of equations. Subsequently, these claims represent no more than a manipulation of basic mathematical constructs, a mathematical algorithm in the abstract. Therefore, Claims 1-10 fail to produce a tangible result, necessitating a rejection under 35 U.S.C. 101. In re Warmerdam, 31 USPQ2d (BNA) 1759 (CAFC 1994).

13. Applicant's system Claims 11-17 are also rejected under tangibility analysis since these Claims, in reciting limitations corresponding to Claims 1-10, are not directed to tangible subject matter even under a means-plus-function interpretation.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. **Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.** Claims 1-17 fail to meet the concreteness criterion of utility set forth in State Street. Consequently, the Claims therefore contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

16. The standard for enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. Factors to be considered when determining a lack of enablement and whether necessary experimentation is undue include the breadth of the claims, the nature of the invention, the state of the prior art, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. MPEP at §2164.01(a). Upon a review of all of the above factors and the evidence as a whole, sufficient reason exists to support a rejection under the enablement requirement.

17. Although Applicant attempts to differentiate the claimed method from certain “trial-and-error” prior art methods (Applicant’s specification at p. 9, l. 12-20), Applicant’s method is inherently “trial-and-error” due to its reliance on Box-Jenkins transfer function methods and other iterative processes disclosed by Applicant. These iterations are either explicitly noted as relying upon the subjective participation of a research analyst or the disclosure is silent with respect to an enabling description of a computer (or algorithmic) implementation of such steps. A detailed discussion of Steps 230-260 is included below.

18. As discussed above at Paragraph 21, the step of determining a relationship (“Step 230”) relies upon the subjective input of a research analyst and implies the necessity of iterations without satisfactorily specifying the criteria upon which such

iterations would rely beyond simply naming model fitting information, reasonable coefficients, and robustness. At least the claimed steps of detecting a lag structure, selecting a functional form, and evaluating the selected functional form ("Step 240," "Step 250," and "Step 260," respectively) similarly rely upon subjective human input and yield results that vary significantly depending on such input.

19. Step 240 includes several sub-steps, Steps 310-360, which are reflected in Claim 8. Applicant's sole disclosed embodiment of Step 240 relies upon the ARIMA model fitting approach pioneered by Box-Jenkins at (sub-) at Step 310. However, as highlighted by the prior art, the Box-Jenkins model requires iterations (Box 1975 at p. 70, Col. 2, l. 13 – p. 71, Col. 1, l. 4) and is dependent on several subjective decisions on the part of the researcher (Newbold, Paul, "The Principles of the Box-Jenkins Approach," *Operational Research Quarterly*, Jul 1975, Vol. 26, No. 2, Part 2, 397-412, herein "Newbold," at p. 397, l. 13-21), the outcomes of the approach varying greatly, including uninterpretable or undesirable results (Newbold at p. 398, l. 10-14, 25-32; p. 409, l. 19 – p. 410, l. 39). Thus, the flexibility provided by the Box-Jenkins Method leads to misuse even by those skilled in the art of time-series data analysis (Newbold at p. 411, l. 27-33). Further, to the extent that Claims 1-17 read on Helmer et al. (Helmer, Richard M. and Johny K. Johansson, "An Exposition of the Box-Jenkins Transfer Function Analysis With an Application to the Advertising-Sales Relationship," *Journal of Marketing Research*, May 1977, Vol. 14, 227-239, herein "Helmer"), discussed in detail starting at Paragraph 69, Applicant's claims lack enablement since many of the model

choices are resolved “on fairly ambiguous bases” and are “a matter of art” (Helmer at p. 230, l. 36-50).

20. Step 250 includes (sub-) Steps 410 and 420, corresponding to the steps of plotting pharmaceutical sales and selecting the functional form recited in Claim 9. As described in the specification at page 7, line 14 – page 8, line 12, the method distinguishes either between a gradual change of slope ($M(t)$ at Eqn. 3) or an abrupt jump ($M(t)$ at Eqn. 4). However, if the market event under consideration “which may impact” product performance does not result in either of these visible effects on product performance data, then Applicant’s method fails at this step to take into account the market event (see previous discussion at Paragraph 20). On the other hand, the teaching of Step 250 may have been intended to limit the type of market event detectable by a research analyst in Step 210 or the method in which the research analyst might detect such market events. In either case, clarification is required to provide enabling disclosure of Step 250.

21. In addition to Steps 230-250, the step of evaluating the selected functional form (“Step 260”) to account also lacks concreteness/enablement for the same reasons as those set forth regarding Step 240. Further, the “if necessary” language additionally requires a particular degree of action that one with ordinary skill would not understand how to put to use with the invention. Applicant’s threshold for necessity is not clearly set forth. Step 260 is described by Applicant as accomplished using the steps of Step 240 (Applicant’s specification at p. 8, l.15).

22. Lastly, the recitation of “one more market events” in the claims may lack enablement in view of the prior art. In particular, Shao provides a method based on Box-Jenkins transfer function and intervention analyses for estimating the impact of multiple marketing strategy events (Shao, Y. Eric, “Multiple Intervention Analysis with Application to Sales Promotion Data,” Journal of Applied Statistics, 1997, Vol. 24, No. 2, 181-191). However, the inclusion of fifteen interventions (corresponding substantially to Applicant’s M(t), “one or more functional forms”) introduced serious problems in estimating model parameters (Shao at p. 185, l. 39-45). Reducing the number of interventions to five by grouping alleviated the noted problem.

23. Therefore, the evidence of record as a whole supports the *prima facie* rejection of Claims 1-17 as failing to comply with the enablement requirement.

24. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

25. **Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

- Claims 1 and 11 recite “market events which may impact said product performance.” It is unclear whether or not impacting product performance is actually required by the claims. For the purpose of expediting examination, the impact limitation is interpreted as optional and non-limiting.

- Claims 1, 6, 11, 15 include “data abnormalities” which is a relative term that renders the claim indefinite. The term “abnormal” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably informed of the scope of the invention. Thus, for the purpose of expediting examination, “abnormality” is interpreted as non-limiting.
- Claim 11, there is no antecedent basis for said abnormality descriptions.

Claim Scope Analysis

26. Applicant has presented new claim language that will now be interpreted by the examiner.

- “determining events which may impact product performance” is taken to merely require determination of an event. The claim does not require that the event is one which impacts performance.
- “generating descriptions” for the product performance and promotions language is taken to be met by the collection of the product prescription sales data subsequent to the promotion introduction.
- “examining” the product and promotion data “to detect and remove” is taken to merely require “examination” of the data. The “to detect and remove” phrases are not taken to represent positive steps, but rather merely hint at the reasoning why examination is done. Further, the detect/remove “any data abnormalities” phrase suggests that detection/removal is not absolutely

necessary where there is no “abnormality” and is further considered to be optional.

- “selecting...forms to account for any impact of...events which may impact” requires selection of a form, yet in the case where events do not impact the performance, the “to account” is essentially optional.
- “evaluating each...form to account *if necessary*” indicates that this accounting is not absolutely necessary and is considered to be optional.

Claim Rejections - 35 USC § 102

27. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

28. **Claims 1, 3-7, and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Basara (Basara, Lisa Ruby, “The Impact of a Direct-To-Consumer Prescription Medication Advertising Campaign on New Prescription Volume,” Drug Information Journal, 1996, Vol. 30, 715-729).**

29. With regard to Applicants’ Claims 1, 6, Basara teaches a method including steps of determining one or more market events (Basara at p. 719, Col. 1, l. 6 – Col. 2, l. 36 teaches mitigating circumstances and other criteria (no competitors), examining product performance and promotion data (the entire crux of Basara is to examine the data;

further Basara teaches selection of a campaign to include a “testable” campaign that is free from a lack of data (taken to represent abnormal data). Further, Basara teaches that the economy and “other factors” can affect sales performance and these external events are accounted for by the introduction of a “noise” component [pg 721 col 2 lines 1-40]. Basara teaches determining a relationship (“an increase”) between each of the one or more promotions and the product (Basara at p. 721, Col. 1, l. 14-46), systematically detecting a promotion lag structure between the one or more promotions and the product performance for the product (Basara at p. 721, Col. 1, l. 48 – p. 723, Col. 2, l. 6), selecting one or more functional forms to account for an impact of each of the one or more determined market events which may impact the product performance (Basara at p. 722, Col. 1, l. 36 – p. 723, Col. 1, l. 12), evaluating each of the selected functional forms to account for the one or more determined market events (Basara at p. 723, Col. 1, l. 13 – Col. 2, l. 6), and quantifying a relationship between the one or more promotions and the product performance for the product by taking into account the evaluated selected functional forms (Basara at p. 723, Col. 2, l. 9 – p. 725, Col. 1, l. 28; Table 2).

30. Regarding claims 3-5, Basara also discloses that the relationship between one or more promotions and product performance includes a quantified portion and a residual portion, and evaluating the residual portion to detect auto-correlation (Basara at p. 721, Col. 2, l. 39 – p. 722, Col. 1, l. 34). Additionally, Basara further discloses evaluating and validating a quantified relationship (Basara at p. 725, Col. 2, l. 1 – p. 728, Col. 1, l. 4), a pharmaceutical product, and manually determining one or more pharmaceutical

market events that may impact pharmaceutical product performance (Basara at p. 719, Col. 1, l. 6 – Col. 2, l. 36), thereby anticipating the limitations of Claim 3-5.

31. Turning now to Claim 7, Basara teaches determining a relationship between each of the one or more promotions and the product to be a relationship selected from the group consisting of multiplicative, additive, or other (Basara at p. 721, Col. 1, l. 14-46).

32. Claims 9 and 10 are also anticipated by Basara. Specifically, Basara teaches the step of selecting a functional form to include plotting sales versus time (Basara at p. 718, l. 10-18) and selecting a functional form (Basara at p. 722, Col. 1, l. 36 – p. 723, Col. 1, l. 12), as well as the step of evaluating the functional form to including graphical evaluation (Basara at Figure 1).

33. Alternatively, Claims 1, 3-7, and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Box 1975. Although the specific examples described within Box 1975 relate to smog data and the consumer price index, Box 1975 states that the disclosed techniques also apply to investigating the possible effect of promotions, advertising campaigns, and price changes on the sale of a product (Box 1975 at p. 70, Col. 1, l. 30-32).

34. Box 1975 teaches all limitations recited in Applicant's Claim 1, including steps of determining one or more market events (Box 1975 at p. 70, Col. 1, l. 10-32; Figure A), determining a relationship between each of one or more promotions and a product (Box 1975 at p. 71, Col. 1, l. 32 – Col. 2, l. 2), detecting a promotion lag structure between

one or more promotions and product performance (Box 1975 at p. 73, Col. 2, l. 4-18), selecting one or more functional forms to account for the impact of each of the one or more determined market events (Box 1975 at p. 71, Col. 2, l. 4 – p. 72, Col. 2, l. 35; p. 73, Col. 2, l. 19-45), evaluating each of the selected functional forms to account for the one or more determined market events (Box 1975 at p. 73, Col. 2, l. 19-45), and quantifying a relationship between the one or more promotions and product performance by taking into account the evaluated functional forms (Box 1975 at p. 73, Col. 2, l. 46 – p. 74, Col. 1, l. 15).

35. In applying Box 1975, the noise figure, N_t , represents the lagged relationship of promotions on product performance where those promotions are different from the market events represented by the intervention terms, ξ_{ij} . N_t , in effect, is a catchall function taking into account the impact on product performance of all factors other than the explicitly specified market events. As described in the reference, fitting the model can make it possible to evaluate the explanatory potential of the noise figure (and therefore the promotion impact) with respect to product performance (Box 1975 at p. 71, Col. 2, l. 32-36). Alternatively, the market event/intervention terms, ξ_{ij} , of Box 1975 can also include one or more promotions, such as several months of advertising expenditure for a single campaign (Box 1975 at p. 72, Col. 2, l. 32-36; see also Wichern at p. 332, l. 1-2) since the reference provides teaching that, generally, ξ_{ij} can be an exogenous time series (Box 1975 at p. 71, Col. 2, l. 25-26). Such an application would leave the noise term to account for market events or, as in Basara, the series of promotions could constitute the market event. Accordingly, the general model set forth by Box 1975

accommodates both interpretations of market events in relation to promotions: (1) a market event being separate from a studied promotion; or (2) a market event including at least one promotion. For an examples of interpretation (1), rejections based on Leone 1987 and Helmer are detailed beginning at Paragraphs 64 and 69, respectively.

36. Box 1975 also anticipates the limitations of Claim 3, including a relationship between the one or more promotions and product performance including a quantified portion and a residual portion, and a step of evaluating the residual portion to detect auto-correlation (Box 1975 at p. 73, Col. 2, l. 10-16; p. 74, Col. 2, l. 16). The quantified and residual portions are inherently taught by the use of transfer function analysis in Box 1975. Additionally, Box 1975 describes a step of evaluating and validating the quantified relationship (Box 1975 at p. 74, Col. 1, l. 16-21), limitations recited in Applicant's Claim 4.

37. With regard to Claim 5, although Box 1975 does not specifically teach a method applied to a pharmaceutical product, Box 1975 applies to pharmaceutical products by teaching, in general, analyzing sales with respect to promotions, price changes, and other events. Moreover, the pharmaceutical limitations in the claims amount to "limiting use" language. However, Applicant provides no explicit or implied reason for distinguishing the analysis of pharmaceutical products from other products. In the absence of evidence supporting such a distinction and given the general applicability of Box-Jenkins transfer function/intervention analysis to many types of time series data (Basara and Applicant's specification at p. 4, l. 22-24), the "pharmaceutical" limitations are not afforded patentable weight. MPEP at §2106(II). Further, the market event

determining step of Box 1975 also includes manual determination of one or more market events (Box 1975 at p. 70, Col. 1, l. 10-32; Figure A).

38. Box 1975 also includes the abnormality examining step limitations of Claim 6 (Box 1975 at p. 76, Col. 1, l. 13-25) and the relationship determining step limitations of Claim 7 (Box 1975 at p. 71, Col. 1, l. 32 – Col. 2, l. 2). Applicant's steps of plotting and selecting in Claim 9 read on the reference (Box 1975 at Figure A; p. 71, Col. 2, l. 47-49; p. 73, Col. 2, l. 19-45), and Claim 10 reads on Box 1975 at least at Figure B.

39. In another alternative application of prior art, Claims 1, 3-5, and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Leone 1987.

40. All limitations of Claim 1 read on the method taught by Leone 1987. Specifically, Leone 1987 discloses steps of determining one or more market events (Leone 1987 at p. 463, l. 5-8; p. 464, l. 1-21), determining a relationship between each of one or more promotions and a product (Leone 1987 at p. 465, l. 1-10), detecting a promotion lag structure between one or more promotions and product performance (Leone 1987 at p. 465, l. 11 – p. 466, l. 6), selecting one or more functional forms to account for the impact of each of the one or more determined market events (Leone 1987 at p. 466, l. 7 – p. 467, l. 3), evaluating each of the selected functional forms to account for the one or more determined market events (Leone 1987 at p. 467, l. 3-5; p. 472, l. 20-41), and quantifying a relationship between the one or more promotions and product performance by taking into account the evaluated functional forms (Leone 1987 at Table 1).

41. In applying Leone 1987, N_t represents the identified and evaluated promotion lag structure. As discussed in the reference, the N_t noise model is very flexible and able to contain multiplicative, seasonal, autoregressive, moving average, and difference terms to accurately reflect the behavior of the system beyond of the explanations provided by the other terms comprising y_t , $(\omega(B)/\delta(B))\xi_t$, which reflect the impact of predetermined market events (Leone 1987 at p. 465, l. 1-39).

42. Following from the use of the Box-Jenkins method, the relationship between the one or more promotions and product performance in Leone 1987 inherently includes a quantified portion and a residual portion (Leone 1987 at p. 465, l. 1-10), and Fig. 1 of Leone 1987 teaches a step of evaluating the residual portion to detect auto-correlation, thereby anticipating Claim 3. Relating to Claim 4, the reference teaches a step of evaluating and validating the quantified relationship (Leone 1987 at p. 472, l. 37-41; p. 473, l. 18-23).

43. In a similar manner as Box 1975, Leone 1987 provides a method relating to pharmaceuticals where the market event determining step includes manually determining one or more pharmaceutical market events (Leone 1987 at p. 463, l. 5-8; p. 464, l. 1-8), thereby anticipating Claim 5. Furthermore, Figs. 6 and 5 of Leone 1987 anticipate Claims 9 and 10, respectively (Leone 1987 at p. 472, l. 3-5, 20-26).

44. **In yet another alternative, Claims 1-5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Helmer.**

45. Helmer teaches Applicant's method as recited in Claim 1, including determining one or more market events (Helmer at p. 230, Col. 1, l. 47 – Col. 2, l. 13), examining the determined one or more market events (Helmer at p. 233, Col. 2, l. 16-22), determining a relationship between each of the one or more promotions and the product (Helmer at Fig. 2 (1); p. 229, Col. 2, l. 8-14; p. 231, Col. 1, l. 3-19), systematically detecting a promotion lag structure between the one or more promotions and the product performance for the product (Helmer at Fig. 2(2)-(6); p. 229, Col. 2, l. 15 – p. 230, Col. 1, l. 46; p. 231, Col. 1, l. 21 – p. 233, Col. 2, l. 5), selecting one or more functional forms to account for any impact of each of the one or more determined market events which may impact product performance (Helmer at Fig. 2(7); p. 230, Col. 1, l. 47 – Col. 2, l. 13; p. 233, Col. 2, l. 7-32), evaluating each of the selected functional forms to account for the one or more determined market events (Helmer at Fig. 2(7); p. 230, Col. 1, l. 47 – Col. 2, l. 13; p. 233, Col. 2, l. 33 – p. 234, Col. 1, l. 24), and quantifying a relationship between the one or more promotions and product performance for the product by taking into account the evaluated selected functional forms (Helmer at Fig. 2(8); p. 230, Col. 2, l. 13-19; p. 234, Col. 1, l. 25 – Col. 2, l. 14).

46. In contrast to the interpretation applied using Box 1975, N_t in Helmer is taken to represent the impact of one or more market events other than the promotions. As described in Helmer, the effects of situational and other unspecified factors are characterized as "noise" or "shocks." N_t represents the composite effect of these factors. Situational and other unspecified factors in Helmer include all factors other than the impact of promotions on sales, which is modeled and quantified by Helmer's Steps

1-6. Therefore, by separately characterizing the noise, the incremental impact of promotions on performance can be measured.

47. The “second diagnostic check” of Helmer further discloses checking for multicollinearity problems, a limitation recited in Applicant’s Claim 2, by detecting cross-correlation between the independent variable and the residuals, which are themselves a function of the independent variable (Helmer at p. 234, Col. 2, l. 29 – p. 235, Col. 1, l.

5). Helmer also describes a relationship between the one or more promotions and product performance including a quantified portion and a residual portion, as well as evaluating the residual portion to detect auto-correlation (Helmer at p. 228, Col. 1, l. 24 – Col. 2, l. 23; p. 234, Col. 2, l. 16-28), limitations recited in Claim 3. Concerning Applicant’s Claim 4, Helmer forecasting ability analysis teaches steps of evaluating and validating a quantified relationship (Helmer at p. 235, Col. 2, l. 3-13; Table 7).

48. Likewise, Helmer teaches the limitations of Claim 5. Helmer’s general teaching of a method for modeling the relationship between advertising (promotion and/or market event) and sales (product performance) encompasses Applicant’s claimed pharmaceutical product, pharmaceutical market events, and pharmaceutical product performance for reasons motivated above at Paragraph 62. Along the same lines, Helmer also provides a general teaching of determining one or market events including a manual determination of such events.

49. With regard to Claim 8, Helmer teaches fitting a univariate auto-regressive model to each of the one or more promotions to determine one or more promotion residual series (Helmer at Fig. 2(2); p. 231, Col. 2, l. 4-14), regressing performance information

for the product to determine a product residual (Helmer at Fig. 2(3)), transforming the product residual into a product residual series (Helmer at Fig. 2(4); p. 231, Col. 2, l. 43 – p. 232, Col. 1, l. 2), determining one or more cross-correlation functions between the one or more promotion residual series and the product residual series (Helmer at Fig. 2(5); p. 232, Col. 1, l. 4 – Col. 2, l. 5), plotting the one or more cross-correlation functions to detect any lagged effect from the one or more promotions corresponding to the one or more cross-correlation functions (Helmer at Fig. 4), and selecting one or more appropriate functional forms which best fits the plotted functions (Helmer at Fig. 2(6); Eqns. 14-15).

Claim Rejections - 35 USC § 103

50. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

51. **Claims 1-10 are alternately rejected under 35 U.S.C. 103(a) as being unpatentable over Helmer in view of Basara.**

52. The methods of Helmer and Basara can be combined to provide a model capable of more accurately identifying the effects of promotions on product performance by further specifying the effect of a market event. Regardless of whether a predetermined market event includes a promotion, the combination of methods taught

by Helmer and Basara specifies a model including terms accounting for the impact of a promotion (or series of promotions) and terms accounting for the impact of a market event distinct from the previously mentioned promotion (or promotions). Generally, Helmer's techniques for identifying and modeling the impact of promotions are combined with Basara's intervention analysis approach for taking into account the effects of a discrete market event.

53. More specifically, with regard to Claim 1, the combination relies upon Helmer to teach the steps of determining a relationship between each of the one or more promotions and the product, and systematically detecting a promotion lag structure between the one or more promotions and the product performance for the product. Basara is relied upon to teach the steps of determining one or more market events, selecting one or more functional forms to account for an impact of each of the one or more determined market events which may impact the product performance, and evaluating each of the selected functional forms to account for the one or more determined market events. Helmer is also applied to teach the step of quantifying a relationship between the one or more promotions and the product performance for the product by taking into account the evaluated selected functional forms. Relevant portions of Helmer and Basara with respect to each anticipated step correspond to those cited in the original rejections under 35 U.S.C. 102(b).

54. Instead of relying only upon Helmer's noise term, N_t , to account for unspecified factors including the effects of a market event (described at Paragraph 71, Basara's intervention analysis, (e.g. a term similar to $[\omega(B)B^b/\delta(B)]I_t$), is incorporated into

Helmer's method to explicitly specify the effect of a predetermined market event, thereby improving the specification and explanatory/predictive power of Helmer's model.

55. With regard to the compatibility of the Helmer and Basara methods, it is noted that both are directed to time-series analysis involving Box Jenkins transfer function analysis for advertising data. Furthermore, intervention analysis is merely an extension of univariate transfer function analysis (Box 1975; Leone 1987 at p. 464, l. 41). As such, intervention analysis is readily combinable with transfer function models. For instance, Hanssens (Hanssens, Dominique M., "Market Response, Competitive Behavior, and Time Series Analysis," *Journal of Marketing Research*, Nov 1980, Vol. 17, 470-85) provides univariate Box-Jenkins and intervention models to account for the potential effects of strikes when estimating the primary demand effects of marketing mix variables (Hanssens at p. 477, Col. 2, l. 1-53; Table 2).

56. Having established the compatibility of the two methods, one of ordinary skill in the art at the time of Applicant's invention would look to combine the teachings of Helmer and Basara to provide a more fully specified model, where econometric model specification is a fundamental factor in the explanatory and predictive effectiveness. In econometrics, models are typically misspecified because of omitted variables (Leone, Robert P., "Modeling Sales-Advertising Relationships: An Integrated Time Series-Econometric Approach," *Journal of Marketing Research*, Vol. 20, Aug 1983, 291-295, at p. 292, Col. 1, l. 32-35). Thus, it would have been obvious to one skilled in the art of time-series data analysis at the time of Applicant's invention to combine the methods of

Helmer and Basara to enhance the specification of Helmer's model, thereby increasing the explanatory and predictive power of the model.

57. The remaining limitations of Claims 2-4 and 8 are taught by Helmer, and the remaining limitations of Claims 5-7 and 9-10 are taught by Basara. Detailed discussion of these rejections are located at least at Paragraphs 52-57 and 69-74 above.

58. **Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Basara, Box 1975, and Leone 1987 in view of Grapentine (Grapentine, Terry, "Managing Multicollinearity," Marketing Research, Fall 1997, Vol. 9, No. 3, 10-21).** The primary references are silent with regard to an explicit step of detecting multicollinearity problems. As described by Grapentine, detection of and correction for multicollinearity is a well known issue in econometric analysis involving a relationship between multiple independent variables, where multicollinearity can lead to falsely insignificant estimates or coefficients with incorrect signs (Grapentine at p. 11, Col. 1, l. 13-16). Each of Basara, Box 1975, and Leone 1987 involves multiple independent variables such as time series inputs and intervention terms. Therefore, it would have been obvious to one skilled in the art at the time of Applicant's invention to modify any one of Basara, Box 1975, and Leone 1987 to include a check for multicollinearity problems to improve the accuracy of a time-series/econometric model.

59. **Claims 6-7 are alternately rejected under 35 U.S.C. 103(a) as unpatentable over Leone 1987 in view of Hillmer (Hillmer, Steven, "Monitoring and Adjusting**

Forecasts in the Presence of Additive Outliers," Journal of Forecasting, Apr-Jun 1984, Vol. 3, No. 2, 205-215).

60. Regarding claim 6, Hillmer remedies the deficiencies of Leone 1987 with respect to Claims 6. Specifically, Hillmer teaches an abnormality examining step including statistically determining data outliers and, if detected, adjusting for the outliers in order to improve forecasting.

61. Regarding claim 7, Leone 1987 teaches a relationship between each of the one or more promotions and the product to be a relationship selected from the group consisting of multiplicative, additive, or other (Leone 1987 at p. 464, l. 9-21).

62. Hillmer is generally directed to methods for adjusting for and detecting additive outliers (non-typical observations) in statistical forecasting, since outliers will negatively affect forecast effectiveness (Hillmer at Abstract). Thus, motivated to improve the forecasting ability of the models set forth in Leone 1987, it would have been obvious to one skilled in the art at the time of Applicant's invention to modify Leone 1987 to include a step of detecting and removing abnormal data outliers as taught by Hillmer.

63. **Claim 8 is alternately rejected under 35 U.S.C. 103(a) as being unpatentable over Leone 1987 in view of Hooley et al. (Hooley, G. J., N. Wilson, and P. Wigodsky, "Modeling the Effects of Advertising: Some Methodological Issues," Journal of the Market Research Society, Jan 1988, Vol. 30, Iss. 1, 45-58, herein "Hooley").** As noted previously, Leone 1987 teaches all limitations of base Claim 1. However, Leone 1987 does not explicitly describe the limitations recited in Claim 8.

64. Hooley remedies the deficiencies of Leone 1987 with respect to Claim 8. In particular, Hooley provides a method of systematically detecting a promotion lag structure including steps of fitting a univariate auto-regressive model to each of the one or more promotions to determine one or more promotion residual series (Hooley at p. 52, l. 24-27; Figure 1), regressing performance information for the product to determine a product residual and transforming the product residual into a product residual series (Hooley at p. 52, l. 27-32; Figure 1), determining one or more cross-correlation functions between the one or more promotion residual series and the product residual series (Hooley at p. 52, l. 33-35), plotting the one or more cross-correlation functions to detect any lagged effect from the one or more promotions corresponding to the one or more cross-correlation functions (Hooley at Table 1), and selecting one or more appropriate functional forms which best fits the plotted functions (Hooley at p. 52, l. 35-42).

65. Generally, Hooley provides an illustration of how Box Jenkins methodology can be applied to identify and include the influence of variables other than advertising prior to econometric modeling (Hooley at Abstract). The ARIMA modeling and cross-correlation techniques described by Hooley advantageously provide a better model than the conventional econometric model (Hooley at p. 57, l. 1-16). Thus, motivated by the enhanced predictive and explanatory power of Hooley's approach, it would have been obvious to one skilled in the art at the time of Applicant's invention to modify Leone 1987's step of detecting promotion lag by applying Hooley's method.

66. **Claim 8 is alternately rejected under 35 U.S.C. 103(a) as being unpatentable over Box 1975 in view of Haugh et al. (Haugh, Larry D. and G.E.P. Box, "Identification of Dynamic Regression (Distributed Lag) Models Connecting Two Time Series," Journal of the American Statistical Association, March 1977, Vol. 72, No. 357, 121-130, herein "Haugh").**

67. As described above at Paragraph 58, Box 1975 teaches all limitations of base Claim 1. However, Box 1975 does not explicitly disclose all limitations of Claim 8. Haugh remedies these deficiencies. Specifically, Haugh provides a method for systematically detecting a promotion lag structure including steps of fitting a univariate auto-regressive model to each of the one or more promotions to determine one or more promotion residual series (Haugh at p. 127, Col. 1, l. 7-9), regressing performance information for the product to determine a product residual and transforming the product residual into a product residual series (Haugh at p. 127, Col. 1, l. 1-4; p. 123, Col. 1, l. 45-52), determining one or more cross-correlation functions between the one or more promotion residual series and the product residual series (Haugh at p. 127, Col. 1, l. 11-13), plotting the one or more cross-correlation functions to detect any lagged effect from the one or more promotions corresponding to the one or more cross-correlation functions (Haugh at Figure A), and selecting one or more appropriate functional forms which best fits the plotted functions (Haugh at Eqn. 4.3). It is also noted that Haugh provides a brief comparison of the disclosed method with the cross-correlation method of the Box 1976 text cited by Applicant (Haugh at p. 129, Col. 2, l. 57 – p. 130, Col. 1, l. 10).

68. Generally, Haugh is directed to methods for identifying distributed lag models relating two time series intended to improve upon current identification methods (Haugh at Abstract; p. 129, Col. 2, l. 17-20). Thus, motivated to improve the detection of the lag structure described in Box 1975, one skilled in the art at the time of Applicant's invention would have found it obvious to modify the step of systematically detecting promotion lag in Box 1975 by applying Haugh's cross-correlation method.

69. Addressing now Applicant's System Claims 11-17, these Claims are further rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Basara, Box 1975, and Leone 1987 or Helmer in view of Didow et al. (Didow, Jr., Nicholas M. and George R. Franke, "Measurement Issues in Time-Series Research: Reliability and Validity Assessment in Modeling the Macroeconomic Effects of Advertising," *Journal of Marketing Research*, Vol. 21, Feb 1984, 12-19, herein "Didow"). The primary references are relied upon for teaching the functional limitations recited in Claims 11-17 (corresponding substantially to Applicant's method Claims 1-5, and 8-9). Specifically, any one of Basara, Box 1975, and Leone 1987 teaches method limitations corresponding to Claims 11, 13-15, and 17, while Helmer teaches method limitations corresponding to Claims 12 and 16.

70. Basara, Box 1975, Leone 1987, and Helmer do not contain explicit teaching that all functions and steps described therein relating to Applicant's claims are implemented on a computer system running standard statistical software. However, Didow describes

the wide availability of computer programs, such as SAS™, for analyzing time series in general. Additionally, Didow notes that such programs would likely spur research of time series in a variety of subjects (Didow at p. 12, Col. 1, l. 11-16).

71. Therefore, it would have been obvious to one skilled in the art at the time of Applicant's invention to implement the methods described by the primary references on a computer running standard off-the-shelf statistical software such as SAS™ to further contribute to research in the social sciences. Additionally, it is noted that merely providing an automatic means to replace a manual activity which accomplishes the same result is not sufficient to distinguish over the prior art. In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958).

Response to Arguments

72. Applicant argues that the research analyst should be familiar with the industry and therefore the claims meet the concreteness requirement. Examiner disagrees. Merely being familiar with the industry at hand does not remove the subjectivity involved with the methodology – the invention is not believed to guarantee reproducibility even between technicians trained in the proper field. Applicant points to a graphical method whereby a “jump” would lead an analyst to correctly specify a model. However, it is not clear what type and/or magnitude of change constitutes the jump. Applicant argues that with trial and error, the right model can be found. This is taken to represent undue experimentation.

73. Applicant argues that Newbold makes clear that experience can increase chances for (methodology) success. Examiner argues this supports his case that the claimed invention does not provide a concrete result because reproducibility is not ensured. Applicant continues to note that “results obtained by different researchers may be different” (again supporting the examiner). The argument that different forecasts for a single data set may both be considered “high-quality” is not convincing as it is the repeatability that is in question, not the quality of any result. Further arguments that certain factors make model choices “more apparent” to the analyst (or one of ordinary skill) still do not provide evidence of guaranteed repeatability.

74. Applicant argues that the claims are tangible and argues that the amended specification cures the rejection. Examiner repeats the rejection because the claims still fall short of providing a tangible result. The claims are taken to result in a mere mathematical relationship unless estimation of the impact of promotion on product performance is also positively claimed.

75. Applicant consistently argues that most if not all references do not provide for selecting a form to account for any event impact, evaluating the form to account if necessary for the event, and quantifying by taking into account the form. As detailed above, most of these steps include optional features whereby the event need not impact the data.

76. Applicant argues that “apart from a noise term”, Basara does not disclose selection of a form to account for market events. First, the noise term can be taken to represent determination of a market event and Basara is taken to select a form to

account for and operate in conjunction with the noise modeling, and to evaluate such form(s).

77. Applicant argues that that Box 1975 fails to select a form to account for an impact of the event and that the noise function is not analyzed until the model is fitted. Simply introducing a noise function into the analysis in combination with selection and evaluation of the form(s) is taken to read on the claims as rejected.

78. Applicant argues that Helmer does not allow the analyst to account for each market event individually and that the noise function is a catch all. These arguments appear to be narrower than the claim language.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey D. Carlson whose telephone number is 571-272-6716. The examiner can normally be reached on Mon-Fri 8a-5:30p, (work from home on Thursdays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Stamber can be reached on (571)272-6724. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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